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Salvatore Albani

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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

NOTIFICATION DATE

DELIVERY MODE

12/14/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DOCKETING@BIOTECHNOLOGYLAWGROUP.COM

| | | | |
|------------------------------|--|--|--|
| Office Action Summary | Application No. 10/614,639 | Applicant(s) ALBANI, SALVATORE | |
| | Examiner G. R. Ewoldt, Ph.D. | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1644

DETAILED ACTION

1. Applicant's amendment and remarks filed 9/25/09 have been entered.
2. Claims 15-20 are under examination.
3. In view of Applicant's amendment the previous objection to Claim 15 has been withdrawn.
4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 20 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, it is unclear what is encompassed by "antibodies or fragments thereof *to that bind to* ligands ...". Applicant is advised that if the intent is to recite antibodies or fragments thereof that specifically bind the ligands of the claims such language would overcome the rejection.

Applicant argues that the instant amendment should render the rejection moot.

Applicant's amendment has not clarified the claim. It is unclear why the first italicized "*to*" above is recited in the claim.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 16-20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,595,881 (of record).

Art Unit: 1644

As set forth previously, The '881 patent teaches a column device comprising a chamber and a solid support further comprising an MHC antigen: functional molecule complex (see, for example column 4, lines 39-52, MHC:anti-MHC antibody complex). Note that the columns used for affinity chromatography inherently meet the limitations of Claims 16-18. Further note that Claims 15 and 20 only limit the claims if the artificial antigen presenting cell option is chosen, however, the claims do not require said option be chosen, thus they still read on the MHC antigen: functional molecule complex.

The reference clearly anticipates the claimed invention.

Note that this rejection was previously withdrawn. A review of the claims, however, reveals that said withdrawal was improper. Independent Claim 19 does not require that the claimed column device comprise any more than the device itself and an MHC: functional molecule complex and that the device be "capable" of binding an artificial APC.

Applicant's arguments, filed 9/25/09, have been fully considered but are not found persuasive. Applicant argues that the column of the reference is not taught as multicompartmentalized nor capable of binding an aAPC.

Applicant admits at page 5 of the remarks that like the claimed device the column of the reference comprises a "chamber". There is no teaching in the instant specification that the "multiplicity of compartments" must consist of any physical barriers or walls, thus, the chamber of the device of the prior art can be considered to be multicompartmentalized. Additionally, any glass or plastic device would be "capable" of binding an aAPC. Indeed, said binding could be direct or even indirect given that the specification provides no guidance in this regard. Accordingly, this limitation is likened to an intended use and provides no patentable weight to the claimed invention.

It is noted that Claim 19 has been amended to include an aAPC in step c). But it is further noted that aAPC is not defined in the specification and is clearly not intended to be limited to an aAPC such as is recited in Claim 15. Accordingly an aAPC might be considered to be a composition capable of binding and activating a T cell, i.e., the invention of the '881 patent.

8. The following are new grounds for rejection necessitated by Applicant's amendment.

Art Unit: 1644

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 15-20 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a written description rejection for the introduction of new matter into the claims.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically a column device comprising a compartment containing an MHC:antigen:functional molecule complex and a generic aAPC.

Applicant has cited no support for the newly claimed invention and none has been found in a review of the jumbo specification.

11. Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of the generic aAPC of Claim 19. As set forth in section 7 above, an aAPC need minimally consist of no more than a means for binding and activating a T cell.

Art Unit: 1644

Clearly then the genus of aAPCs is large and varied, ranging from at least the aAPC of the '881 patent to the aAPC Claim 15 of the instant claims. But while said minimal function (binding and activating a T cell) are described, said means (i.e., structure) are not. Given these facts, and that the specification provides only an adequate written description of the aAPC of Claim 15, one of skill in the art would conclude that the specification fails to adequately describe the column device comprising the generic aAPC of Claim 19. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

12. No claim is allowed.

13. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0878.

15. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications

Art Unit: 1644

is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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